K120247

JUN 21 2012

510(k) Summary
EasyDeX

Submitter
Vineland Syrup Inc.
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Vineland, New Jersey 08360
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Contact Person
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President
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Date of Summary Submission
January 23, 2012

Device Identification
Trade Name: EasyDeX
Device Name: Drink, Glucose Tolerance
Classification: II
Product Code: MRV
Regulation #: 862.1345

Device to Which Substantial Equivalence is Claimed
Glucose Tolerance Beverage
Perk Scientific, Inc.
520 Commerce Dr.
Yeadon, PA 19050
510(k) Number: K032753

Device Description
EasyDeX is a water-based flavored beverage containing specific quantities of dextrose (d-glucose). The product is manufactured in two (2) flavors (Fruit Punch and Orange) and three (3) concentrations.

Intended Use

EasyDex is a flavored non-carbonated beverage containing specific quantities of dextrose (D-glucose). The manufactured beverages contain three (3) different quantities of glucose; 50, 75, and 100 grams quantities per 10 oz. bottle. This product is used in the administration of an in Vitro Diagnostic Glucose Tolerance Test in the evaluation of diabetes mellitus and other related disease conditions. This product is for oral consumption only.

Performance Summary

This device has the same technological characteristics (composition and packaging) as the predicate device. The product is manufactured under strict Current Good Manufacturing Practices to the specifications set by the World Health Organization and the American Diabetes Association for this type of product. All products will be tested and certified both in-house and by an independent laboratory for sugar composition and concentration.
The device is as safe, as effective, and performs as well or better than the predicate device.

The above statements contain information that is covered in the main body of the 510(k) and does not contain unsubstantiated labeling claims, does not contain trade secrets or confidential commercial information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

JUN 21 2012

Vineland Syrup, Inc
c/o Eric Feerst
57 Hartford Road
Sewell, NJ 08080

Re: k120247
Trade Name: EasyDeX
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: MRV
Dated: April 20, 2012
Received: April 26, 2012

Dear Mr. Feerst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k120247

Device Name: EasyDeX

Indications for Use:

EasyDeX is a flavored non-carbonated beverage containing specific quantities of dextrose (D-glucose). The manufactured beverages contain three (3) different quantities of glucose; 50, 75, and 100 grams quantities per 10 oz. bottle. This product is used in the administration of an in Vitro Diagnostic Glucose Tolerance Test in the evaluation of diabetes mellitus and other related disease conditions. This product is for oral consumption only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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